



12-21-04

PATENT
144002-2001

1647
[Signature]

Applicant : Douglas T. Dieterich
Serial No. : 09/862,404
Filed : May 21, 2001
Title : METHOD OF TREATING ANEMIA CAUSED BY RIBAVIRIN
TREATMENT OF HEPATITIS C USING ERYTHROPOIETIN ALPHA
Art Unit : 1647
Examiner : Regina M. Deberry

745 Fifth Avenue
New York, NY 10151

EXPRESS MAIL

Mailing Label Number: EV206810554US

Date of Deposit: December 20, 2004

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" Service under 37 CFR 1.10 on the date indicated above and is addressed to the Honorable Commissioner of Patents and Trademarks, Washington, DC 20231.

Adam Ahmed
(Typed or printed name of person mailing paper or fee)

[Signature]
(Signature of person mailing paper or fee)

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The Examiner's attention is respectfully invited to the following documents, which are also listed on the accompanying Form PTO-1449, enclosed.

U.S. PATENT DOCUMENT

1. US Patent No. 5,399,551, "Enhancer for the antianemia effect of erythropoietin and method of augmenting the antianemia effect of erythropoietin," Ise et al., March 21, 1995.

OTHER PRIOR ART

1. Bizollon T, U Palazzo, C Ducerf, M Chevallier, M Elliott, J Baulieux, M Pouyet, C Trepo, "Pilot study of the combination of interferon alfa and ribavirin as therapy of recurrent hepatitis C after liver transplantation," HEPATOLOGY, (1997), 26(2):500-504. (abstract)

2. Dieterich DT, "Hepatitis C Virus and Human Immunodeficiency Virus: Clinical Issues in Coinfection," The American Journal of Medicine, December 27, 1999, Vol 107(6B):79S-83S.

3. Dieterich DT, R Wasserman, N Brau, TI Hassanein, EJ Bini, PJ Bowers, MS Sulkowski, "Once-Weekly Epoetin Alfa Improves Anemia and Facilitates Maintenance of Ribavirin Dosing in Hepatitis C Virus-Infected Patients Receiving Ribavirin Plus Interferon Alfa". THE AMERICAN JOURNAL OF GASTROENTEROLOGY, VOL. 98, No. 11, (2003).

4. Dieterich DT, KB Weisz, DJ Goldman, ML Malicdem, "Combination Treatment with Interferon (IFN) and Ribavirin (RBV) for Hepatitis C (HCV) in HIV Co-Infection Patients," HEPATOLOGY, AASLD Abstract 422, Vol.30, No.4, Pt.2, (October 1999).

5. Manns MP, JG McHutchison, SC Gordon, VK Rustgi, M Shiffman, R Reindollar, AD Goodman, K Koury, M Ling, JK Albrecht, "Peginterferon alfa-2b plus ribavirin compare with interferon alfa-2b plus ribavirin for initial treatment of chronic hepatitis C: a randomised trial," THE LANCET, Vol. 358, September 22, 2001.

6. McHutchison JG, JE Ware Jr., MS Bayliss, S Pianko, JK Alrecht, S Cort, I Yang, MP Neary, "The effects of interferon alpha-2b in combination with ribavirin on health related quality of life and work productivity," JOURNAL OF HEPATOLOGY, 34 (2001) 140-147.
7. Mocroft A, O Kirk, SE Barton, M Dietrich, R Proenca, R Colebunders, C Pradier, A Monforte, B Ledergerber, JD Lundgren, "Anaemia is an independent predictive marker for clinical prognosis in HIV-infected patients from across Europe," AIDS 1999, Vol. 13:943-950.
8. Nezam AH, DT Dieterich, PJ Pockros, ER Schiff, ML Shiffman, MS Sulkowski, T Wright, Z Younossi, BL Goon, KL Tang, PJ Bowers, "Epoetin Alfa Maintains Ribavirin Dose in HCV-Infected Patients: A Prospective, Double-Blind, Randomized Controlled Study," GASTROENTEROLOGY, (2004), 126:1302-1311.
9. Wasserman R, N Brau, TI Hassanein, E Bini, M Sulkowski, D Dieterich, "Once weekly epoetin alfa increases hemoglobin and decreases RBV discontinuation among HCV patients who develop anemia on RBV/INF therapy," HEPATOLOGY (October 2000), AASLD Abstracts, No. 833.
10. Weisz K, S Kreiswirth, M McMeeking, J Braun, J Tirelli, AH Talal, DT Dieterich, "Erythropoietin Use For Ribavirin/Interferon Induced Anemia In Patients With Hepatitis C," HEPATOLOGY, AASLD Abstract 501, (October 1998).

This Supplemental Information Disclosure Statement is not a representation that the documents cited herein are considered most pertinent, or that a search has been undertaken, or that any of the cited documents are indeed prior art. The Examiner is invited to undertake an independent search. Applicant asserts that the claimed invention is patentable over these documents.

Applicant respectfully requests that the Examiner consider and make of record the documents cited herein and that a copy of Form PTO-1449, appropriately initialed by the Examiner, be returned to Applicant's attorney.

It is believed no fee is due, however, the Examiner is authorized to charge any deficit or credit any overpayment to Deposit Account No. 50-0320.

Respectfully submitted,

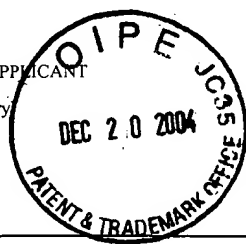
FROMMER LAWRENCE & HAUG LLP
Attorney for Applicant

By: _____



Grace L. Pan
Reg. No. 39,440
(212) 588-0800

Based on Form PTO-1449 (3/90)	ATTY. DOCKET NO. 144002-2001	SERIAL NO. 09/862,404
LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary)	APPLICANT Douglas T. Dieterich	
	FILING DATE May 21, 2001	GROUP 1647



U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
AA	US Patent No. 5,399,551	March 21, 1995.	Ise et al.			
AB						

FOREIGN PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS								
i		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

AC		Bizollon T, U Palazzo, C Ducerf, M Chevallier, M Elliott, J Baulieux, M Pouyet, C Trepo, "Pilot study of the combination of interferon alfa and ribavirin as therapy of recurrent hepatitis C after liver transplantation," HEPATOLOGY, (1997), 26(2):500-504. (abstract)
AD		Dieterich DT, "Hepatitis C Virus and Human Immunodeficiency Virus: Clinical Issues in Coinfection," The American Journal of Medicine, December 27, 1999, Vol 107(6B):79S-83S.
AE		Dieterich DT, R Wasserman, N Brau, TI Hassanein, EJ Bini, PJ Bowers, MS Sulkowski, "Once-Weekly Epoetin Alfa Improves Anemia and Facilitates Maintenance of Ribavirin Dosing in Hepatitis C Virus-Infected Patients Receiving Ribavirin Plus Interferon Alfa". THE AMERICAN JOURNAL OF GASTROENTEROLOGY, VOL. 98, No. 11, (2003).
AF		Dieterich DT, KB Weisz, DJ Goldman, ML Malicdem, "Combination Treatment with Interferon (IFN) and Ribavirin (RBV) for Hepatitis C (HCV) in HIV Co-Infection Patients," HEPATOLOGY, AASLD Abstract 422, Vol.30, No.4, Pt.2, (October 1999).
AG		Manns MP, JG McHutchison, SC Gordon, VK Rustgi, M Shiffman, R Reindollar, AD Goodman, K Koury, M Ling, JK Albrecht, "Peginterferon alfa-2b plus ribavirin compare with interferon alfa-2b plus ribavirin for initial treatment of chronic hepatitis C: a randomised trial." THE LANCET, Vol. 358, September 22, 2001.
AH		McHutchison JG, JE Ware Jr., MS Bayliss, S Pianko, JK Alrecht, S Cort, I Yang, MP Neary, "The effects of interferon alpha-2b in combination with ribavirin on health related quality of life and work productivity," JOURNAL OF HEPATOLOGY, 34 (2001) 140-147.
AI		Mocroft A, O Kirk, SE Barton, M Dietrich, R Proenca, R Colebunders, C Pradier, A Monforte, B Ledergerber, JD Lundgren, "Anaemia is an independent predictive marker for clinical prognosis in HIV-infected patients from across Europe," AIDS 1999, Vol. 13:943-950.
AJ		Nezam AH, DT Dieterich, PJ Pockros, ER Schiff, ML Shiffman, MS Sulkowski, T Wright, Z Younossi, BL Goon, KL Tang, PJ Bowers, "Epoetin Alfa Maintains Ribavirin Dose in HCV-Infected Patients: A Prospective, Double-Blind, Randomized Controlled Study," GASTROENTEROLOGY, (2004), 126:1302-1311.
AK		Wasserman R, N Brau, TI Hassanein, E Bini, M Sulkowski, D Dieterich, "Once weekly epoetin alfa increases hemoglobin and decreases RBV discontinuation among HCV patients who develop anemia on RBV/INF therapy," HEPATOLOGY (October 200?), AASLD Abstracts, No. 833.
AL		Weisz K, S Kreiswirth, M McMeeking, J Braun, J Tirelli, AH Talal, DT Dieterich, "Erythropoietin Use For Ribavirin/Interferon Induced Anemia In Patients With Hepatitis C." HEPATOLOGY, AASLD Abstract 501, (October 1998).
AM		
AN		
AO		
AP		

EXAMINER

DATE CONSIDERED

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.